



TABLE OF CONTENTS

Page

I.	Real Party in Interest	2
II.	Related Appeals and Interferences	2
III.	Status of Claims.....	2
IV.	Status of Amendments.....	2
V.	Summary of the Claimed Subject Matter	2
VI.	Grounds of Rejection to be Reviewed on Appeal	7
VII.	Arguments	7
A.	Claims 1-7 are Not Obvious under 35 U.S.C. § 103(a) over Ballantyne in view of Joao and further in view of Summerell.....	8
B.	Claims 8-14 Are Not Obvious under 35 U.S.C. § 103(a) over Ballantyne et al and Joao in view of Seare	11
C.	Claims 15-21 and 23-25 are Not Obvious under 35 U.S.C. § 103(a) over Ballantyne and Joao in view of Russek and further in view of Soll et al	13
D.	Claim 22 is Not Obvious under 35 U.S.C. § 103(a) over Ballantyne et al, Joao, Russek, Soll et al in view of Official Notice.....	15
E.	Conclusion.....	16
VIII.	Claims Appendix	17
IX.	Evidence Appendix.....	25
X.	Related Proceedings Appendix.....	26



PATENT

39994A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Glenn P. Vonk et al.

Serial No.: 09/881,041

Filed: June 15, 2001

For: A HEALTH OUTCOMES AND DISEASE
MANAGEMENT NETWORK AND
RELATED METHOD FOR PROVIDING
IMPROVED PATIENT CARE

Confirmation No. 5157

Group Art Unit: 3626

Examiner: Thomas, Joseph

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an appeal pursuant to 35 U.S.C. § 134 from the Examiner's decision rejecting claims 1-25 as set forth in the final Office Action of August 22, 2007 and further in Advisory Action mailed March 17, 2008.

I. Real Party in Interest

The real party in interest in this application and the appeal is Becton Dickinson and Company by an assignment recorded September 6, 2002 on Reel 013266, Frame 0424.

II. Related Appeals and Interferences

There are no other related patents or applications related to this invention on appeal or that are involved in an interference proceeding.

III. Status of Claims

Claims 1-25 are pending and are the subject of this appeal. Claims 1-25 stand finally rejected and are reproduced in the Claims Appendix (Section VIII).

IV. Status of Amendments

Amendments to the claims were filed on August 8, 2007 and were entered in the August 22, 2007 final rejection.

V. Summary of the Claimed Subject Matter

Briefly, the present invention is directed a health outcomes and disease management network and related method for providing improved healthcare. A network 102 of healthcare managers and healthcare providers 106 interactively cooperate with patients or clients 112 to enroll clients in the network with a plan of care, monitor and evaluate patient status to provide the most appropriate treatment for the patients in the most cost-effective manner, thus improving overall healthcare. The network 102 aggregates data to reveal population trends and outcomes, and provide rapid feedback and information on the best medical/economic practices to the local networks.

Independent claim 1 recites a system for monitoring health-related conditions of patients, comprising:

a plurality of remote monitoring stations (Fig. 1., 112, 114, ¶44), each being configured to receive patient health-related data pertaining to a respective patient; and

a computer network (Fig. 1, 102) comprising a database (Fig. 1, 104, ¶44, ¶46) containing accumulated health-related data pertaining to health-related conditions and treatments that reveals population trends and outcomes and at least one data access device configured to provide a health care provider (Fig. 1, 106, ¶45) access to said computer network and said database, said computer network configured to receive (¶44) said patient health-related data pertaining to respective patients from said remote monitoring stations and provide a health care provider with electronic treatment establishment tools (¶46, ¶¶90-92) to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and said computer network configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices (¶46, ¶79, ¶117, ¶120) that can be made for different ones of the health-related conditions;

said remote monitoring stations (Fig. 1., 112, 114) being configured with electronic self-management tools (¶25, ¶26, ¶71, ¶99) for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools;

said computer network (Fig. 1, 102) being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress (¶76) of the patient on the selected treatment program and whether information relating to the selected treatment program needs to be conveyed (¶78, ¶95) to the patient in response to said progress determination.

Independent claim 8 recites a method for monitoring health-related conditions of patients, comprising:

obtaining patient health-related data pertaining to patients at a plurality of remote monitoring stations (Fig. 1, 112, 114, ¶44), each being configured to receive respective said patient health-related data from a respective said patient;

storing accumulated health-related data pertaining to health-related conditions and treatments that reveals population trends and outcomes in a database (Fig. 1, 104, ¶44, ¶46) of a computer network (Fig. 1, 102);

receiving at said computer network said patient health-related data from said remote monitoring stations (Fig. 1, 112, 114) pertaining to respective patients (¶44);

controlling said computer network (Fig. 1, 102) to provide a health care provider with electronic treatment establishment tools (¶46, ¶¶91-92) to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data;

controlling said computer network (Fig. 1, 102) to revise said accumulated health-related data based on said patient health-related data (¶46, ¶79, ¶117, ¶120);

generating from said accumulated health-related data clinical data comprising outcomes of said treatment programs (¶76, ¶112);

receiving economic data relating to protocols used in said treatment programs (¶¶78-79);

aggregating said patient health-related data, said clinical data and said economic data with said accumulated health-related data comprising population outcomes and generic standards of care (¶79, 1440 in Fig. 4B, care step 10 in Fig. 9A); and

determining from said aggregated data recommendations for improving the treatment programs (¶¶79-80, 1440 in Fig. 4B, care step 10 in Fig. 9A).

Independent claim 15 recites a method for managing health-related conditions of patients, comprising:

assigning healthcare managers (Fig. 1, 106) to said patients (Fig. 1, 112), such that each said healthcare manager is assigned to a respective group of said patients (¶51, ¶53, 1100 and 1200 in Fig. 3);

collecting healthcare data by using each said healthcare manager to collect respective patient health-related data for each respective patient in their said group of patients (§59, 1200 in Fig. 3);

determining whether each respective patient is suitable for participation in a treatment program (§§54-55, 1130 in Fig. 4A);

controlling a computer network (Fig. 1, 102, §44) to receive said health-related data from each of said healthcare managers, and to store said patient health-related data pertaining to each said patient in a database, said database (Fig. 1, 104, §44, §46) further including accumulated data pertaining to health-related conditions and treatments that reveals population trends and outcomes;

coordinating each said healthcare manager with at least one member of a primary care team to establish a treatment program for each respective patient in their said group of patients based on said patient health-related data pertaining to that respective patient and said accumulated data (§67); and

updating said accumulated data in said database based on said patient health-related data provided by said healthcare managers and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions (§46, §79, §117, §120);

wherein the determining step comprises the steps of

obtaining agreement from a respective patient to participate in a treatment program (§57, 1140 in Fig. 4A); and

receiving approval from a payer who will pay for the treatment program (§55);

wherein the controlling step comprises the steps of

receiving health-related data for a respective patient comprising assessment of the patient's medical, psychosocial and environmental conditions (§60, 1220 in Fig. 4A);

receiving a plan of care initiated by the corresponding one of the healthcare managers assigned to the patient as a result of an interview with the patient and the

assessment, the plan of care being used in the establishment of the treatment program for the patient (§51, §§60-61, §64).

Independent claim 23 recites a method of establishing a treatment program for a patient comprising:

assigning healthcare managers to patients (§51, §53, 1100 and 1200 in Fig. 3);

determining whether each of said patients is suitable for participation in a treatment program (§54, §55, 1130 in Fig. 4A);

collecting healthcare data by using said healthcare managers to collect respective patient health-related data for each of their assigned said patients, said healthcare managers developing a respective client plan of care (CPOC) for each of their assigned said patients by interviewing them if they are selected for participation, and developing a medical plan of care (MPOC) comprising a treatment program for each of their assigned said patients in cooperation with a primary care team comprising at least one of primary care physicians, hospitals and specialists (§51, §§60-61, 1200 in Fig. 3, 1220 and 1240 in Fig. 4A);

controlling a computer network (Fig. 1, 102) to receive said patient health-related data from each of said healthcare managers (Fig. 1, 106), and to store said patient health-related data pertaining to each of said patients in a database (Fig. 1, 104, §44, §46), said database further including accumulated data pertaining to health-related conditions and treatments that reveals population trends and outcomes;

coordinating said healthcare managers with at least one member of the primary care team to ensure the treatment programs are followed by respective said patients, tracking any changes to the MPOC and updating members of the primary care team regarding the changes (§67, 1240 in Fig. 4A); and

updating said accumulated data in said database (Fig. 1, 104) based on said patient health-related data provided by said healthcare managers (Fig. 1, 106), including revisions to the CPOCs and MPOCs for respective said patients and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions (§63, §79).

VI. Grounds of Rejection to be Reviewed on Appeal

The grounds of rejection for review on appeal are:

- (a) whether claims 1-7 are unpatentable under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,867,821 to Ballantyne et al (hereinafter “Ballantyne”) in view of U.S. Patent No. 6,283,761 to Joao (hereinafter “Joao”), and further in view of U.S. Patent No. 5,937,387, to Summerell et al (hereinafter “Summerell”);
- (b) whether claims 8-14 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Ballantyne et al and Joao in view of U.S. Patent No. 5,557,514, to Seare et al (hereinafter “Seare”);
- (c) whether claims 15-21 and 23-25 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Ballantyne et al and Joao in view of U.S. Patent No. 5,319,355 to Russek (hereinafter “Russek”) and further in view of U.S. Published Application No. 2003/0055679, to Soll et al (hereinafter “Soll”); and
- (d) whether claim 22 is unpatentable under 35 U.S.C. § 103(a) as being obvious over Ballantyne, Joao, Russek, Soll et al in view of Official Notice.

VII. Arguments

The independent claims 1, 8 and 15 recite storing accumulated health-related data pertaining to health-related conditions and treatment that reveals population trends and outcomes in a database of a computer network, and patient health-related data pertaining to respective patients. Further, each of these claims recites that the accumulated health-related data is revised or updated based on the patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions. Thus, recitation of these two different types of data makes it clear that simply updating the patient health-related data is not the same as updating or revising accumulated health-related data that reveals population trends and identifying improvements in standards of care and medical practices. As discussed below, the Applicants submit that none of the applied references discloses or suggests singly, or in combination, a system that aggregates data

revealing population trends and outcomes, and modifies the accumulated health-related data based on patient health-related data for identification of improvements in medical practices.

In the Advisory Action, the Examiner states that Applicants' arguments appear to consider references individually, and not in the manner combined by the Examiner in the prior rejections. The Examiner states that arguments regarding the Summerell reference are based on Applicants "viewing the teachings of Summerell in a vacuum." Applicants respectfully submit that attacking a reference combined with others on an individual basis is proper when Applicants are arguing that the reference fails to teach the premise on which the Examiner purports that it teaches. The Applicants have explained below a number of instances where a reference cited by the Examiner in a rejection applying a combination of references does not teach the premise the Examiner purports the reference to teach.

A. Claims 1-7 are Not Obvious under 35 U.S.C. § 103(a) Over Ballantyne in view of Joao and further in view of Summerell

In the Office Action, Ballantyne is relied on to purportedly teach:

"a computer network comprising a database containing accumulated health-related data pertaining to health-related conditions and treatment that reveals population trends and outcomes and at least one data access device configured to provide a health care provider access to said computer network and said database, said computer network configured to receive said patient health-related data pertaining to respective patients from said remote monitoring stations and provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and said computer network being configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions," as recited in claim 1.

The referenced sections of Ballantyne and the remainder of Ballantyne, however, merely refer to the storage of patient medical health records and not to accumulated data relating to population trends and outcomes, nor revision of this data to identify improvements of standards of care and medical practices.

On pages 24-25 of the “Response to Arguments” section of the final Office Action, the Examiner states “that a broad, yet reasonable interpretation of Applicant’s claim language reads on the teachings of Ballantyne...That is, patient medical records (i.e., health-related data pertaining to conditions and treatment) do reveal various information, including, but not limited to, population trends and outcomes.” Applicants respectfully disagree.

Claim 1 recites, among other limitations, (1) remote monitoring stations that receive “patient health-related data pertaining to a respective patient;” (2) a database in a computer network containing “accumulated health-related data pertaining to health-related conditions and treatments that reveals population trends and outcomes;” and (3) the computer network being “configured to *revise said accumulated health-related data based on said patient health-related data* for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions.”

The patient’s electronic medical record described in Ballantyne contains only patient-specific information and not health-related data pertaining to health-related conditions and treatments that reveal population trends and outcomes as claimed. See, for example, col. 15, line 40 through col. 16, line 13 of Ballantyne. The storage of plural patient electronic medical records at the master library of Ballantyne and the regional medical library of Ballantyne also do not teach or suggest the inventions recited in claims 1, 8 and 15. The storing of different patient electronic medical records in the master library, and the acquiring of information on specific medical research fields by the regional library, described in Ballantyne do not teach revising the acquired information based on the patient medical records. By contrast, claims 1, 8 and 15 recite revising or updating said accumulated health-related data based on said patient health-related data received at the computer network from a remote monitoring station or healthcare manager.

The Office Action admits that Ballantyne fails to disclose:

- (1) *“said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient’s lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools”*; and
- (2) *“said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information relating to the selected treatment program needs to be conveyed to the patient.”*

The Office Action relies on (1) Summerell and (2) Joao, respectively, to purportedly teach these claim limitations. On page 25 of the “Response to Arguments” section of the final Office Action, the Examiner states that he disagrees with Applicants’ earlier contention that Summerell does not disclose an electronic self-management tool that allows a patient to integrate a health care provider’s established treatment program, but rather seeks to provide a tool for users to select their own wellness plan without involvement of a health care provider. The Examiner cites Fig. 2 and column 4, lines 15-19 and states that these citations can be broadly construed to read on “health care provider.” Applicants respectfully disagree. Fig. 2 is an introductory page for a user who is a patient and not a health care provider. As stated on column 8, lines 53-65 of Summerell, the patient is guided to enter personal information. As stated in column 5, lines 47-53 and lines 60-62 of Summerell, the wellness measurement and wellness options systems disclosed therein seek to reduce the difficult and time-consuming data collection task of physicians by providing systems that “collect data directly from the patient.” Thus, the Examiner’s broad interpretation of Summerell is in contradistinction to what the reference actually teaches. The reliance on column 4, lines 15-19 of Summerell in support of the Examiner’s position is also a misinterpretation. The questions to be asked of a doctor mentioned column 4, lines 15-19 of Summerell refer to questions to ask as a patient “progresses in the personalized wellness program” that is set up as a result of the patient using the system, that is, *after* the system is used by the patient to set up and obtain his/her wellness program. Thus, the health care provider is not involved in the set up of the program as the Examiner suggests. The physician can merely augment the data entered by the patient into the system with test results (e.g., patient’s blood pressure). See column 5, lines 60-67 of Summerell.

In view of the foregoing, the 35 U.S.C. § 103(a) rejection of claim 1 and its dependent claims 2-7 is respectfully requested.

B. Claims 8-14 Are Not Obvious under 35 U.S.C. § 103(a) over Ballantyne et al and Joao in view of Seare

For similar reasons stated above in connection with claim 1, neither Ballantyne nor Summerell singly or in combination teaches the following recitations of method claim 8 which are similar to apparatus claim 1:

“storing accumulated health-related data pertaining to health-related conditions and treatment that reveals population trends and outcomes in a database of a computer network;

receiving at said computer network said patient health-related data from said remote monitoring stations pertaining to respective patients;

controlling said computer network to provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data;

controlling said computer network to revise said accumulated health-related data based on said patient health-related data,” among other limitations.

Seare and Joao do not overcome these deficiencies. Even if Seare or Joao could arguably be reasonably interpreted to disclose said accumulated health-related data that reveals population trends and outcomes as claimed, Applicants respectfully submit that there is nothing in either of these two references that discloses or suggests revising said accumulated health-related data based on said patient health-related data from remote monitoring stations, or determining from said aggregated data recommendations for improving treatment programs. As stated above, Joao discloses using the disclosed system 10 to determine if a diagnosis and/or treatment is “in-line” with *current standards* for the given healthcare field (see column 28, lines 38-48), but is silent regarding storing accumulated data revealing population trends and outcomes, and revising said accumulated based on patient health-related data, and determining recommendations for improving treatment programs, as recited in claim 8. The response described in column 38, lines 55-56 of Joao can include an evaluation of a diagnosis and/or prescribed treatment that is apart from the patient’s response to the prescribed treatment, and

therefore does not suggest determining improvements from outcomes as claimed but rather only determines if the diagnosis and/or treatment is “in-line” with *current standards* for the given healthcare field described earlier in Joao at column 28, lines 38-48.

In the Office Action, Seare et al is relied on to purportedly teach the following claim recitations:

*“receiving economic data relating to protocols used in said treatment programs;
aggregating said patient health-related data, said clinical data and said economic data with said accumulated health-related data comprising population outcomes and generic standards of care; and
determining from said aggregated data recommendations for improving the treatment programs.”*

Seare et al teaches “converting raw medical providers billing data into an informative historical database” (see column 4, lines 34-36) to provide a mechanism for assessing medical services utilization patterns of medical providers and thereby generating statistically-generated medical provider utilization profiles.

Applicants respectfully submit, for reasons stated above, that Ballantyne does not disclose a computer network for establishing treatment programs for said patients based on their respective patient health-related data and accumulated health-related data, as recited in claim 8. Seare et al does not overcome this deficiency and therefore does not teach or suggest receiving economic data relating to protocols used in these treatment programs.

In addition, Seare et al does not disclose or suggest aggregating population outcomes and generic standards of care with other data, as recited in claim 8. Joao is relied on in the Office Action to purportedly teach the recited clinical data comprising outcomes of the treatment programs established by the claimed computer network. Applicants respectfully submit that, while Joao briefly mentions treatment monitoring and evaluation of treatment progress, Joao does not disclose generating clinical data comprising outcomes of treatment programs.

Seare et al uses historical medical provider billings to statistically establish utilization profiles. As indicated in Fig. 4 of Seare et al, a medical provider diagnosis indicated in the billing data can have one of three outcomes, that is, resolution, return to chronic disease state, or

complication of the disease. If Seare et al can provide outcome information from medical provider billing data that may arguably teach clinical data as claimed, then such outcome data cannot be population outcome information as claimed.

Further, since the outcomes in Fig. 4 of Seare et al are only available from the raw billing data, they are not population outcomes as claimed. Seare et al uses CPT and other codes for reporting a medical service (see column 6, lines 7-9) and different tables to determine episodes of care to be included in the analysis and creation of a utilization profile for a medical provider. One table provides a numerical factor to adjust the frequency of a code based on age or gender in determining the provider's profile. This, however, only relates to that providers' medical services as evidenced in his billing records and not to outcomes of a population aggregated with the outcomes of medical services provided by that medical provider.

Since Seare et al does not overcome the deficiencies of Ballantyne et al and Joao, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 8-14 is respectfully requested.

C. Claims 15-21 and 23-25 are Not Obvious under 35 U.S.C. § 103(a) over Ballantyne and Joao in view of Russek and further in view of Soll et al

Applicants respectfully submit that Ballantyne does not teach accumulated health-related data as recited in independent claims 15 and 23 for the reasons stated above in connection with amended claim 1.

Applicants respectfully submit that neither Ballantyne nor Joao teaches updating said accumulated health-related data based on said patient health-related data, or identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions above in connection with amended claim 1 or 8.

In the Office Action, Soll et al is relied on to purportedly teach the following claim 15 recitations, among others:

*“determining whether each respective patient is suitable for participation in a treatment program;
wherein the determining step comprises the steps of
obtaining agreement from a respective patient to participate in a treatment program; and
receiving a plan of care initiated by the corresponding one of the healthcare managers assigned to the patient as a result of an interview with the patient and the*

assessment, the plan of care being used in the establishment of the treatment program for the patient.”

In Soll et al, the abstract is silent regarding determining if a patient is suitable for participation in a treatment program. The interview in paragraph [0058] of Soll et al and relied on in the Office Action refers to patient exit and revisit interviews to assess response to treatment and therefore relates to after any plan of care or treatment is administered. Nothing in Soll et al discloses or suggests receiving a plan of care as a result of an interview for use in the establishment of a treatment program. Further, for reasons stated above in connection with claims 1-7, Ballantyne does not disclose a establishing a treatment program for respective patients based on their respective patient health-related data and accumulated data relating to health-related conditions and treatments. In addition, neither Soll et al, Joao, nor Russek overcome the deficiencies of Ballantyne et al, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 15-20 is respectfully requested.

Claims 16-20 are not rendered obvious for reasons stated above in connection with claims 1-7.

Regarding claims 21 and 32, the referenced section of Joao is silent regarding a CPOC and MPOC as claimed. Column 4, lines 40-47 of Joao describe a database that can be accessed to provide treatment plans or programs, among other things. This section of Joao, however, is silent regarding developing a CPOP during a interview, or a MPOC via a primary care team member. The interview described in Soll et al is a patient exit and revisit interview and not an interview to develop a client plan of care.

Claim 23 recites determining whether each respective patient is suitable for participation in a treatment program and therefore is not rendered obvious for the reasons stated above in connection with claim 15.

In the Office Action, Joao is relied on to purportedly teach the following recitations of claim 23 which has been amended herein:

“coordinating said healthcare managers with at least one member of the primary care team to ensure the treatment programs are followed by respective said patients, tracking any changes to the MPOC and updating members of the primary care team regarding the changes; and

updating said accumulated data in said database based on said patient health-related data provided by said healthcare managers, including revisions to the CPOCs and MPOCs for respective said patients and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions.”

For reasons stated above in connection with claim 1, Joao does not teach updating said accumulated data or identifying improvements in standards of care and medical practices as claimed.

In view of the foregoing, independent claim 23 and its dependent claims 24 and 25 are not rendered obvious by the applied references herein. In addition, regarding claim 24, the referenced text at column 16, lines 38-65 of Joao lists patient data but is silent regarding documenting for storage patient-related communications during scheduled conferences and non-scheduled communications such as messages or an interview or conference communication.

D. Claim 22 is Not Obvious under 35 U.S.C. § 103(a) over Ballantyne et al, Joao, Russek, Soll et al in view of Official Notice

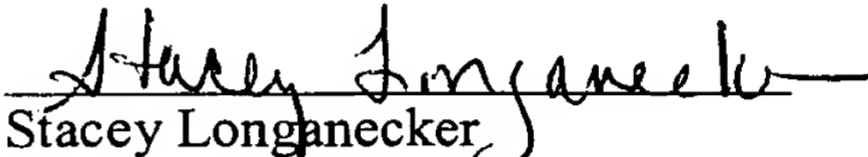
In the Final Office Action, the Examiner admits that Ballantyne et al fails to expressly disclose a method as claimed in claim 15 and instead takes Official Notice. In the Advisory Action, the Examiner asserts that Applicants did not properly traverse the Official Notice. Applicants respectfully disagree.

The Examiner takes Official Notice of excluding patients from treatment programs based on various criteria by giving only the example of a minor. Claim 22, however, also recites excluding a patient from a treatment program based on the criteria that the patient cannot communicate effectively. No example or other statement was given by the Examiner of such an exclusion being old and notoriously well known. In the Amendment filed June 8, 2007, the Applicants traversed the rejection of claim 22 based on Official Notice and requested references for at least the disclosure of excluding a patient from a treatment program based on the criteria that the patient cannot communicate effectively. Further, Applicants submit that the Examiner's use of Official Notice was improper per MPEP 2144.03 since it was the principle evidence on which the rejection was based and not was not employed merely to fill the gaps.

E. Conclusion

For the reasons presented herein, Applicants submit that claims 1-25 are not rendered obvious under 35 U.S.C. § 103(a) by the cited references of record. Accordingly, reversal of the final rejection is requested, and allowance of claims 1-25 is respectfully requested.

Respectfully submitted,


Stacey Longanecker
Reg. No. 33,952

Roylance, Abrams, Berdo & Goodman, L.L.P.
1300 19th Street, N.W., Suite 600
Washington, D.C. 20036
(202) 659-9076

Dated: April 22, 2008

VIII. CLAIMS APPENDIX

1. (Previously Presented) A system for monitoring health-related conditions of patients, comprising:

a plurality of remote monitoring stations, each being configured to receive patient health-related data pertaining to a respective patient; and

a computer network comprising a database containing accumulated health-related data pertaining to health-related conditions and treatments that reveals population trends and outcomes and at least one data access device configured to provide a health care provider access to said computer network and said database, said computer network configured to receive said patient health-related data pertaining to respective patients from said remote monitoring stations and provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and said computer network configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions;

said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools;

said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information relating to the selected treatment program needs to be conveyed to the patient in response to said progress determination.

2. (Previously Presented) A system as claimed in claim 1, wherein:

each of said remote monitoring stations comprises at least one measuring device, configured to measure a physiological condition of said respective patient, and to provide data

representative of said physiological condition for inclusion among said patient health-related data; and

said electronic assessment tools are configured to allow a health care provider to monitor said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle and determine readiness of the patient for self-management under the selected treatment program.

3. (Previously Presented) A system as claimed in claim 1, wherein:

said remote monitoring stations are configured to provide said patient health-related data to said computer network over the Internet.

4. (Previously Presented) A system as claimed in claim 1, wherein:

said electronic assessment tools are selected from the group consisting of Standard Form-36 (SF-36), Duke Activity Index, guidelines of the Diabetes Quality Improvement Project (DQIP), tools for specific disease state monitoring, depression scales, nutrition assessment tools, quality of life assessment tools.

5. (Previously Presented) A system as claimed in claim 1, wherein:

said computer network is configured to generate reports, each including health-related information pertaining to a respective said patient.

6. (Previously Presented) A system as claimed in claim 1, wherein:

said computer network is configured to provide said accumulated health-related data stored in said database to organizations financing at least a portion of said treatment programs, and is configured to receive financial data pertaining to said treatment programs from said organizations and to store said financial data in said database.

7. (Previously Presented) A system as claimed in claim 1, wherein:

each said remote monitoring station receives from its respective said patient said patient health-related data including data pertaining to the cardiovascular system of said patient.

8. (Previously Presented) A method for monitoring health-related conditions of patients, comprising:

obtaining patient health-related data pertaining to patients at a plurality of remote monitoring stations, each being configured to receive respective said patient health-related data from a respective said patient;

storing accumulated health-related data pertaining to health-related conditions and treatments that reveals population trends and outcomes in a database of a computer network;

receiving at said computer network said patient health-related data from said remote monitoring stations pertaining to respective patients;

controlling said computer network to provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data;

controlling said computer network to revise said accumulated health-related data based on said patient health-related data;

generating from said accumulated health-related data clinical data comprising outcomes of said treatment programs;

receiving economic data relating to protocols used in said treatment programs;

aggregating said patient health-related data, said clinical data and said economic data with said accumulated health-related data comprising population outcomes and generic standards of care; and

determining from said aggregated data recommendations for improving the treatment programs.

9. (Original) A method as claimed in claim 8, wherein:

each of said remote monitoring stations includes at least one measuring device; and

said obtaining includes controlling said at least one measuring device at each said remote monitoring station to measure a physiological condition of its respective patient to provide data representative of said physiological condition for inclusion among said patient health-related data.

10. (Original) A method as claimed in claim 8, wherein:
said receiving includes transmitting said patient health-related data from said monitoring stations over the Internet to said computer network.
11. (Original) A method as claimed in claim 8, further comprising:
providing a health care provider access to said computer network and said database via at least one data access device.
12. (Original) A method as claimed in claim 8, further comprising:
controlling said computer network to generate reports, each including health-related information pertaining to a respective said patient.
13. (Previously Presented) A method as claimed in claim 8, wherein said receiving step comprises:
controlling said computer network to provide said accumulated health-related data stored in said database to organizations financing at least a portion of said treatment programs, and to receive financial data pertaining to said treatment programs from said organizations and to store said financial data in said database.
14. (Original) A method as claimed in claim 8, wherein:
said obtaining step includes controlling each said remote monitoring station to receive from its respective said patient said health related data including data pertaining to the cardiovascular system of said patient.
15. (Previously Presented) A method for managing health-related conditions of patients, comprising:
assigning healthcare managers to said patients, such that each said healthcare manager is assigned to a respective group of said patients;

collecting healthcare data by using each said healthcare manager to collect respective patient health-related data for each respective patient in their said group of patients;

determining whether each respective patient is suitable for participation in a treatment program;

controlling a computer network to receive said health-related data from each of said healthcare managers, and to store said patient health-related data pertaining to each said patient in a database, said database further including accumulated data pertaining to health-related conditions and treatments that reveals population trends and outcomes;

coordinating each said healthcare manager with at least one member of a primary care team to establish a treatment program for each respective patient in their said group of patients based on said patient health-related data pertaining to that respective patient and said accumulated data; and

updating said accumulated data in said database based on said patient health-related data provided by said healthcare managers and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions;

wherein the determining step comprises the steps of

obtaining agreement from a respective patient to participate in a treatment program; and

receiving approval from a payer who will pay for the treatment program;

wherein the controlling step comprises the steps of

receiving health-related data for a respective patient comprising assessment of the patient's medical, psychosocial and environmental conditions;

receiving a plan of care initiated by the corresponding one of the healthcare managers assigned to the patient as a result of an interview with the patient and the assessment, the plan of care being used in the establishment of the treatment program for the patient.

16. (Previously Presented) A method as claimed in claim 15, wherein:

said collecting includes using a respective remote monitoring station to obtain respective said patient health-related data from each respective said patient.

17. (Previously Presented) A method as claimed in claim 15, wherein:
said controlling controls said computer network to receive said patient health-related data from at least some of said health-care managers via the Internet.
18. (Previously Presented) A method as claimed in claim 15, further comprising:
controlling said computer network to provide said accumulated health-related data stored in said database to organizations financing at least a portion of said treatment programs, and receive financial data pertaining to said treatment programs from said organizations and to store said financial data in said database.
19. (Original) A method as claimed in claim 15, further comprising:
controlling said computer network to generate reports, each including health-related information pertaining to a respective said patient.
20. (Previously Presented) A method as claimed in claim 15, wherein:
respective said patient health-related data for each said respective patient includes data pertaining to the cardiovascular system of said respective patient.
21. (Previously Presented) A method as claimed in claim 15, wherein collecting healthcare data comprises said healthcare managers developing a client plan of care (CPOC) and a medical plan of care (MPOC), the CPOC is developed during the interview with the patient, and the MPOC is developed with at least one member of the primary care team.
22. (Previously Presented) A method as claimed in claim 15, wherein the determining comprises excluding a respective patient based on selected criteria comprising the patient is a minor, the patient has not received a selected diagnosis, and the patient cannot communicate effectively, and including a respective patient based on selected criteria comprising having a selected primary diagnosis, and being at risk for future hospital admissions.

23. (Previously Presented) A method of establishing a treatment program for a patient comprising:

assigning healthcare managers to patients;

determining whether each of said patients is suitable for participation in a treatment program;

collecting healthcare data by using said healthcare managers to collect respective patient health-related data for each of their assigned said patients, said healthcare managers developing a respective client plan of care (CPOC) for each of their assigned said patients by interviewing them if they are selected for participation, and developing a medical plan of care (MPOC) comprising a treatment program for each of their assigned said patients in cooperation with a primary care team comprising at least one of primary care physicians, hospitals and specialists;

controlling a computer network to receive said patient health-related data from each of said healthcare managers, and to store said patient health-related data pertaining to each of said patients in a database, said database further including accumulated data pertaining to health-related conditions and treatments that reveals population trends and outcomes;

coordinating said healthcare managers with at least one member of the primary care team to ensure the treatment programs are followed by respective said patients, tracking any changes to the MPOC and updating members of the primary care team regarding the changes; and

updating said accumulated data in said database based on said patient health-related data provided by said healthcare managers, including revisions to the CPOCs and MPOCs for respective said patients and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions.

24. (Previously Presented) A method as claimed in claim 23 further comprising:

scheduling conferences between said patients and said members of the primary care team; and

documenting patient-related communications comprising at least one of messages, an interview communication and conference communication during the conference and during non-scheduled patient-related communications for storage in said database.

25. (Previously Presented) A method as claimed in claim 23 further comprising:
- said healthcare managers following clinical encounter schedules to communicate with their said patients;
 - using scripts to communicate with said patients during the clinical encounters; and
 - assessing said patients' physical and psychological responses.

IX. EVIDENCE APPENDIX

No evidence under 37 C.F.R. § 1.130, 1.131 or 1.132 is relied upon in this Appeal.

X. RELATED PROCEEDINGS APPENDIX

None